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Benzocaine Otic Solution

DEFINITION
Benzocaine Otic Solution contains NLT 90.0% and NMT 110.0% of the labeled amount of benzocaine ($C_9H_{11}NO_2$).

IDENTIFICATION
- **A.** The retention time of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.
- **B.** The UV spectrum of the major peak of the *Sample solution* corresponds to that of the *Standard solution*, as obtained in the *Assay*.

ASSAY
- **Procedure**

Solution A: 0.1% Trifluoroacetic acid, prepared by diluting 1.0 mL of trifluoroacetic acid with water to 1 L

Solution B: Acetonitrile

Mobile phase: See *Table 1*.

Table 1

Time (min)	Solution A (%)	Solution B (%)
0	90	10
34	50	50
35	90	10
38	90	10

Diluent: *Solution A* and *Solution B* (1:1)

System suitability solution: 1 µg/mL each of USP Benzocaine RS, USP Aminobenzoic Acid RS, and USP Ethyl 4-Nitrobenzoate RS in *Diluent*. Sonicate to dissolve, if necessary.

Standard solution: 0.1 mg/mL of USP Benzocaine RS in *Diluent*. Sonicate to dissolve, if necessary.

Sample solution: Nominally 0.1 mg/mL of benzocaine in *Diluent* prepared as follows. Transfer a portion of Otic Solution, equivalent to 10 mg of benzocaine, into a 100-mL volumetric flask and dissolve it in *Diluent*.

Chromatographic system
(See *Chromatography ⟨621⟩, System Suitability*.)

Mode: LC

Detector: UV 280 nm. For *Identification* test *B*, use a diode array detector in the range of 200–400 nm.

Column: 4.6-mm × 25-cm; 5-µm packing L7

Flow rate: 1.5 mL/min

Injection volume: 20 µL

System suitability

Samples: *System suitability solution* and *Standard solution*

Suitability requirements

Resolution: NLT 6 between aminobenzoic acid and benzocaine, and between benzocaine and ethyl 4-nitrobenzoate, *System suitability solution*

Tailing factor: NMT 1.5, *Standard solution*

Relative standard deviation: NMT 1.0%, *Standard solution*

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of the labeled amount of benzocaine ($C_9H_{11}NO_2$) in the portion of Otic Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of benzocaine from the *Sample solution*

r_S = peak response of benzocaine from the *Standard solution*

C_S = concentration of USP Benzocaine RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of benzocaine in the *Sample solution* (mg/mL)

Acceptance criteria: 90.0%–110.0%

IMPURITIES

• **Organic Impurities**

Solution A, Solution B, Mobile phase, Diluent, and **Chromatographic system:** Proceed as directed in the *Assay*.

Standard solution: 1 µg/mL each of USP Benzocaine RS, USP Aminobenzoic Acid RS, and USP Ethyl 4-Nitrobenzoate RS in *Diluent*. Sonicate to dissolve, if necessary.

Sample solution: Nominally 0.5 mg/mL of benzocaine in *Diluent* prepared as follows. Transfer a portion of Otic Solution, equivalent to 50 mg of benzocaine, into a 100-mL volumetric flask, dissolve, and dilute with *Diluent* to volume.

System suitability

Sample: *Standard solution*

[Note—See *Table 2* for relative retention times.]

Suitability requirements

Resolution: NLT 6 between aminobenzoic acid and benzocaine, and between benzocaine and ethyl 4-nitrobenzoate

Relative standard deviation: NMT 3.0% for each peak corresponding to benzocaine, aminobenzoic acid, and ethyl 4-nitrobenzoate

Analysis

Samples: *Standard solution* and *Sample solution*

Calculate the percentage of aminobenzoic acid and ethyl 4-nitrobenzoate in the portion of Otic Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of aminobenzoic acid or ethyl 4-nitrobenzoate from the *Sample solution*

r_S = peak response of the corresponding Reference Standard from the *Standard solution*

C_S = concentration of USP Aminobenzoic Acid RS or USP Ethyl 4-Nitrobenzoate RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of benzocaine in the *Sample solution* (mg/mL)

Calculate the percentage of any individual unspecified degradation product in the portion of Otic Solution taken:

$$\text{Result} = (r_U/r_S) \times (C_S/C_U) \times 100$$

r_U = peak response of any individual unspecified degradation product from the *Sample solution*

r_S = peak response of benzocaine from the *Standard solution*

C_S = concentration of USP Benzocaine RS in the *Standard solution* (mg/mL)

C_U = nominal concentration of benzocaine in the *Sample solution* (mg/mL)

Acceptance criteria: See *Table 2*. Disregard peaks less than 0.05%.

Table 2

Name	Relative Retention Time	Acceptance Criteria, NMT (%)
Aminobenzoic acid	0.3	0.20
Benzocaine	1.0	—
Ethyl 4-nitrobenzoate	2.1	0.20
Any individual unspecified degradation product	—	0.20
Total impurities	—	1.0

SPECIFIC TESTS

• **Microbial Enumeration Tests ⟨61⟩** and **Tests for Specified Microorganisms ⟨62⟩:** It meets the requirements of the tests for absence of *Salmonella* species and *Escherichia coli* and for absence of *Staphylococcus aureus* and *Pseudomonas aeruginosa*. The total aerobic microbial count is less than 10^2 cfu/mL.

ADDITIONAL REQUIREMENTS

• **Packaging and Storage:** Preserve in tight, light-resistant containers.

• **USP Reference Standards ⟨11⟩**

USP Aminobenzoic Acid RS

Benzoic acid, 4-amino.

$C_7H_7NO_2$ 137.14

USP Benzocaine RS

USP Ethyl 4-Nitrobenzoate RS

Benzoic acid, 4-nitro-, ethyl ester.

$C_9H_9NO_4$ 195.17

Auxiliary Information - Please check for your question in the FAQs before contacting USP.

Topic/Question	Contact	Expert Committee
BENZOCAINE OTIC SOLUTION	Documentary Standards Support	SM52020 Small Molecules 5

Chromatographic Database Information: Chromatographic Database

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